PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	05.10.2004
Applicant's or agent's file reference	**IMPORTANT NOTIFICATION**
08-892370WO	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA 03/00964	27.06.2003	28.06.2002

Applicant
UNIVERSITY OF GUELPH et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Faux, K Tel. +49 89 2399-8062

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 08-892370WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/CA 03/00964	International filing date *(day/month/year)* 27.06.2003	Priority date *(day/month/year)* 28.06.2002
International Patent Classification (IPC) or both national classification and IPC A01H5/00		
Applicant UNIVERSITY OF GUELPH et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
14.01.2004	05.10.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Burkhardt, P Telephone No. +49 89 2399-7456

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA 03/00964

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-36 as originally filed

Sequence listings part of the description, Pages

1-10 as originally filed

Claims, Numbers

1-20 received on 30.08.2004 with letter of 27.08.2004

Drawings, Sheets

1/13-13/13 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☒ contained in the international application in written form.

   ☒ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 1 - 20 (all partially)

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 1 - 20 (all partially)

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1 - 20
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1 - 20
Industrial applicability (IA)	Yes:	Claims	1 - 20
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item I
Basis of the report

The amended claims filed with the letter of 27.08.2004 are formally acceptable under Article 34(2)(b) PCT.

Re Item III
No opinion

1. In response to an invitation of the ISA to restrict the claims or pay additional search fees the applicant neither restricted the claims nor paid additional fees. Consequently, only invention 1 was searched and this report will also be limited to invention 1.

2. The reasons for the non-unity objection were as follows:

   2.1 Article 3(4)iii PCT and Rule 13.2 PCT stipulate that where a group of inventions is claimed the requirements of unity shall be fulfilled only where there is a technical relationship among those inventions involving one or more of the same corresponding special technical features. "Special" technical features are those features that define a contribution which each of the inventions makes over the prior art.

   2.2 The only corresponding technical feature linking the different groups of inventions is that they all relate to genes form *Medicago sativa* that are allegedly harvest-inducible. Such genes, however, are already known from the prior art (e.g. WO0173090). Therefore, this feature cannot provide a common inventive concept for potential inventions 1 - 3.

   2.3 The applicant was requested to note that the alleged function of an gene, i.e. being harvest-inducible, is a non-distinctive characteristic and would not render the subject-matter of claim 1 novel over the prior art.

   2.4 Consequently, there is lack of unity, and the different inventions not belonging to a common inventive concept, had been divided into different groups pursuant to Article 17(3)(a) PCT:

Invention 1 (Claims 1 - 26, all partially)

relating to a harvest-inducible cDNA (SEQ ID NO:1), the corresponding regulatory element (SEQ ID NO:4), a method for their isolation, vectors and plants containing said regulatory element and to methods for the production of heterologous proteins in plants employing said regulatory element.

Invention 2 (Claims 1 - 26, all partially)

relating to a harvest-inducible cDNA (SEQ ID NO:2), the corresponding regulatory element (SEQ ID NO:5), methods for their isolation, vectors and plants containing said regulatory element and to methods for the production of heterologous proteins in plants employing said regulatory element.

Invention 3 (Claims 1 - 26, all partially)

relating to a harvest-inducible cDNA (SEQ ID NO:3), the corresponding regulatory element (SEQ ID NO:6), methods for their isolation, vectors and plants containing said regulatory element and to methods for the production of heterologous proteins in plants employing said regulatory element.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The following documents (D) are referred to; the numbering is following the order of the International Search Report:

D1 Ferullo *et al.*, 1996. Crop Sci 36:1011-1016.
D2 Matz and Lukyanov, 1998. Nucl. Acids Res. 26:5537-5543.
D3 Kuhn, 2001. Ann. Bot. 87:139-155.
D4 WO-A-0173090 (Samuel Roberts Noble Foundation)

1. Article 33(2)(3) PCT (Novelty and inventive step)

1.1 Present claim 1 is directed to a regulatory element (SEQ ID NO:4) having

harvest-inducible regulatory activity.

1.2 It appears that subject-matter closely related to SEQ ID NO:4 could meet the requirements of Articles 33(2)(3) PCT as the prior art does not disclose or suggest a regulatory element of SEQ ID NO:4.

1.3 The claim, however, reads on to fragments or complement of fragments of SEQ ID NO:4, and to nucleic acids that hybridise to a fragment or complement of SEQ ID NO:4. Thus it relates to subject-matter that is neither sufficiently disclosed (Article 5 PCT) nor supported by the description (Article 6 PCT). In addition an undue burden is placed on others trying to establish the extent of protection and it would require undue experimentation to reduce the claimed subject-matter to practice (Article 5 PCT).

1.4 Moreover, the description and the prior art do not provide credible evidence that any fragment or complement of SEQ ID NO:4 or sequences hybridising to these fragments or complements would solve the technical problem, i.e. the provision a regulatory element having harvest-inducible regulatory activity. Present claim 1 does not meet the requirements of Article 33(3) PCT. The same holds true for dependent claims 2 - 20.

1.5 The applicant is requested to note that functional statements like "having harvest-inducible regulatory activity" do not correct this deficiency. The subject-matter of a claim should be defined in terms of technical features of the invention which would be a nucleic acid sequence that indeed possesses the claimed function.